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| MEDICINELODGE INC. 180 SOUTH 600 WEST LOGAN, UT 84321 | | | EXAMINER BLATT, ERIC D | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/688,746

Applicant(s)

SINNOTT ET AL.

Examiner

Eric Blatt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SE/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21-24, 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Borzone et al. (US 5,814,070) in view of Winters et al. (US 6,569,186).

Regarding claims 21-24, Borzone discloses a disuse retention system (Figure 6) comprising a suture anchor 34 wherein the suture anchor comprises an elongated body having a proximal end and an opposing distal end displaced from the proximal end along a longitudinal axis, wherein a first suture port 38 extends through at least a portion of the body; and a helical thread wound about and outwardly projecting from the elongated body (Figure 6). There is at least a first portion (portion of port 38 nearest the proximal face) of the first suture port extends substantially parallel to the longitudinal axis. The first suture port is spaced apart from the longitudinal axis so as to not intersect the longitudinal axis, and the elongated body is formed as a single, unitary piece. The first suture port extends distally of a proximal end of the helical thread and intersects the helical thread. At least a second portion (portion of port 38 extending around the anchor) of the first suture port extends nonparallel to the longitudinal axis.

Regarding claims 27-28, Borzone discloses that the system further comprises at least one suture positionable through at least the first suture port (Column 4, Lines 1-25), and a tool 50 configured to interface with the suture anchor to facilitate driving the suture anchor into bone (Figure 7).

Thus, Borzone discloses all elements of claims 21-24 and 27-28 except for the first suture port being fully encircled by an interior surface along at least a portion of its length. Winters discloses a related tissue retention system (Figures 3, 4, and 7) wherein a suture enters a suture port having longitudinal portions that are fully encircled by an interior surface at the proximal face of the retention device. The suture enters one of said fully encircled longitudinal portions, and then leaves this fully encircled portion to curve around the exterior body of the device before entering a second fully enclosed portion of the suture port at the proximal end of the retention device. This system allows the suture to be easily seen and manipulated as it wraps around the exterior body of the device while also offering the more secure fixation offered by a port that is entirely encircled by an interior surface of the device. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Borzone by providing the suture port such that the proximal longitudinal portions of said suture port are fully encircled by an interior surface in order to enable a more secure fixation as taught by Winters.

Regarding claim 26, Borzone does not disclose that a bore extends fully through the body along the longitudinal axis, wherein the first suture port is positioned such that the first suture port is not in communication with the bore. The driving tool of Borzone

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interfaces with the outside of the proximal end of the suture anchor. Winters discloses an alternate system for driving a suture anchor wherein the suture anchor comprises a bore having a substantially hexagonal drive feature, wherein the bore passes through the body of the anchor along the longitudinal axis, and a driving tool that interfaces with the interior of said bore. (Figures 5, 6B, and 9-10) It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Borzone by providing the driving system disclosed in Winters since this system was a known alternative and its substitution would have produced expected results. As taught by Winters, the bore of the modified device is not in communication with the suture port.

Claims 25, 29-36, 45-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Borzone et al. (US 5,814,070) in view of Winters et al. (US 6,569,186) as applied to claims 21-24, 26-28 above, and further in view of Wenstrom, Jr. et al. (US 6,045,573).

Regarding claims 25, 35, and 36, Borzone in view of Winters teach all elements of claims 25, 35, and 36 as previously discussed except that a second suture port extends through a portion of the body, wherein the first and second suture ports are arranged symmetrically about the longitudinal axis. Wenstrom discloses that it was known to provide a second suture port, such that the first and second suture ports are arranged symmetrically about the longitudinal axis. (Figure 1, Column 2) It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Borzone by providing a second suture port, similar to the first port, such

that the first and second suture ports are arranged symmetrically about the longitudinal axis for purposes such as allowing the suture anchor to anchor more than one thread as taught by Wenstrom. It also would have been obvious to one of ordinary skill in the art at the time of the invention to provide a second suture portion for purposes such as allowing the device to achieve more soft tissue fixation as taught by Wenstrom. (Column 2, Lines 1-20) The device shown in Figure 6 of Borzone has a single port comprising two holes into the proximal face on opposite sides with and a transverse portion wrapping half-way around the anchor to connect the two holes. Upon modifying the device, the device would have two ports, each comprising two holes into the proximal face and a transverse portion connecting them. As taught by Winters, the modified ports have fully encircled proximal longitudinal port portions that communicate with the transverse open port portions.

Regarding claims 29-35, the modified device holds first and second suture portions wherein the first and second suture portions are separate pieces from each other. At least a portion of the first and second suture ports extend distally from the proximal end of the helical thread, and the first and second suture ports are displaced from the longitudinal axis. (Figure 6) At least a portion of each of the first and second suture ports extends nonparallel to the longitudinal axis. The fully encircled proximal longitudinal port portions communicate with the transverse portions of the ports. Looking at Figure 6 of Borzone, the proximal longitudinal portions of the ports connect to the transverse portions along an exterior sidewall of the elongated body of the device.

Thus, each of the sutures, following the paths of the ports, extends through an exterior sidewall of the elongated body distal to the fully encircled portions of the ports.

Regarding claims 45, 48, 51, 53, and 54, the first and second suture ports of the modified device each comprise two fully encircled apertures. Each of said four total apertures are configured to receive an intermediate suture portion such that the first and second suture ports cooperate to provide four parallel suture lengths extending proximally from said four apertures of the proximal end. A first portion of each of the first and second suture ports extends parallel to the longitudinal axis, and a second portion extends nonparallel to the longitudinal axis.

Regarding claims 46 and 47, the first suture port intersects an exterior sidewall of the elongated body so as to communicate with a first opening of the exterior side wall, and the second suture port intersects the exterior sidewall so as to communicate with a second opening of the exterior sidewall. The first and second openings intersect the helical thread. It should be noted that the modified ports of the device shown in Figure 6 of Borzone comprise transverse grooves cut into the exterior of the device such that said transverse grooves are not completely surrounded by the material of the device. Said transverse portions of the ports are cut into the exterior side walls to allow an opening for the suture to pass around the device. Thus, these portions are considered openings in the exterior side walls.

Regarding claims 49 and 50, as previously stated, the modified device of Borzone has two suture ports, each comprising two apertures into the proximal end face and a transverse portion connecting them. Suture may be threaded through each hole.

Reinterpreting each hole to be a suture port, the anchor comprises first, second, third, and fourth suture ports, each intersecting the proximal end face so as to communicate with first, second, third, and fourth openings of the proximal end face respectively. The first suture port adjoins the third suture port via the first transverse portion between them so as to facilitate positioning a first intermediate suture portion within the first and third suture ports. The second suture port adjoins the fourth suture port via the second transverse portion so as to facilitate positioning a second intermediate suture portion within the second and fourth suture ports.

Regarding claim 52, the driving tool of Borzone interfaces with the outside of the proximal end of the suture anchor. Winters discloses an alternate system comprising a bore having a substantially hexagonal drive feature that interfaces with a driving tool. It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the device of Borzone with a substantially hexagonal drive feature positioned to receive torque from a tool to facilitate driving the suture anchor into bone as taught by Winters.

Claims 37-40 and 42-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Borzone et al. (US 5,814,070) in view of Winters et al. (US 6,569,186) as applied to claim 26 above, and further in view of Graf et al. (US 2002/0042615).

Regarding claims 37-40 and 42-44, the modified device comprises a bore extending fully through the body along the longitudinal axis. The first suture port

extends distally of a proximal end of the helical thread and intersects the helical thread. A second portion of the first suture port extends nonparallel to the longitudinal axis. There is a tool configured to interface with the suture anchor to facilitate driving the suture anchor into bone.

Thus, Borzone in view of Winters teach all elements of claims 37-40 and 42-44 as previously discussed except for the bore terminates proximal to the distal end of the body. Graf discloses a retention device comprising a bore for receiving a tool that extends only through a portion of the body of the device and terminates proximal to the distal end of the body. It would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the apparatus of Borzone by having the longitudinal bore terminate proximal to the distal end of the body since Graf teaches this was a well known alternative and such a modification would not have produced unexpected results.

Claims 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Borzone et al. (US 5,814,070) in view of Winters et al. (US 6,569,186) and Graf et al. (US 2002/0042615) as applied to claim 37 above, and further in view of Wenstrom, Jr. et al. (US 6,045,573).

Borzone in view of Winters and Graf teach all elements of claim 41 as previously discussed except for a second suture port extending through at least a portion of the body wherein the first and second suture ports are symmetrically arranged about the longitudinal axis. Wenstrom discloses that it was known to provide a second suture

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port, such that the first and second suture ports are arranged symmetrically about the longitudinal axis. (Figure 1, Column 2) It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Borzone by providing a second suture port, similar to the first port, such that the first and second suture ports are arranged symmetrically about the longitudinal axis for purposes such as allowing the suture anchor to anchor more than one thread as taught by Wenstrom.

Response to Arguments

Applicant's arguments with respect to claims 21-25, 27-32, 34-40, 42-51, and 53-54 have been considered but are moot in view of the new ground(s) of rejection.

Regarding claim 26, Applicant argues that "Claim 26 depends from claim 21 and is patentable for the reasons set forth in the discussion of claim 21." In the discussion of claim 21, Applicant argues that the embodiment shown in Figure 6 of Borzone does comprise a suture port that is fully encircled by an interior surface along at least a portion of its length. Claim 26 is rejected over Borzone in view of Winters. As discussed above in the body of the rejection, Examiner holds that Winters remedies the aforementioned deficiency.

Applicant submitted no arguments with respect to claims 33, 41, or 52.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric Blatt whose telephone number is (571)272-9735. The examiner can normally be reached on Monday-Friday, 9:00 AM-6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin T. Truong/
Primary Examiner, Art Unit 3734

Eric Blatt
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